

Appl. No. : 10/031,913
Filed : 05/21/2002

REMARKS

In response to the Office Action mailed November 16, 2005, Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the following comments. No claims have been amended, added or canceled by this paper. Accordingly, Claims 18-28 and 73-81 remain pending, Claims 1-17 and 29-72 having been canceled previously. Because no claims have been amended by this paper, the listing of claims section has been omitted.

The Combination of Wang and Mishra Is Improper

Claims 18-28 and 73-81 presently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wang in view of Mishra. Specifically, the Examiner has taken the position that it would have been obvious to combine Wang and Mishra by replacing the outer tube of the Wang catheter with the outer membrane of the Mishra dialysis probe. Furthermore, the Examiner responded to the prior arguments of the Applicants by stating that "the Wang device would work just as well or better with the teachings of Mishra. The inner tube of Wang distributes the fluid along the length of the catheter. The outer tube is merely an exit area for the fluid that is being distributed. Changing the exit area to a different material or porosity does not change the uniform distribution of the fluid created by the inner member." Paragraph 5 of the Office Action mailed November 16, 2005.

Applicants respectfully disagree. The Examiner's position cannot be supported by the disclosure of Wang, and is simply incorrect. As argued in the prior amendment, the Wang catheter depends on both the inner and outer catheter tubes in order to provide a uniform flow rate along the length of the infusion section of the catheter. Specifically, the exit holes of the inner tube and the exit holes of the outer tube are strategically positioned relative to one another to vary the average fluid flow distance from the lumen of the inner tube, through the lumen between the tubes, and out the exit holes of the outer tube. This variance in the average fluid flow distance along the infusion section of the Wang catheter compensates for the reduced flow rate through the distal exit holes in comparison to the proximal exit holes. See column 3, lines 37-60 of the Wang reference. Thus, the Examiner's position that the Wang catheter would function as well with the outer tube replaced by the outer membrane of Mishra is incorrect.

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Moreover, the Examiner's proposed modification would clearly change the principle of operation of the Wang reference. The Wang reference achieves a uniform flow rate along the length of the infusion section by strategically positioning discrete exit holes on both the inner tube and outer tube of the catheter. Neither the inner tube nor the outer tube can be replaced with a porous membrane and still achieve the desired variance in the average flow distance of the fluid exiting the catheter. M.P.E.P. § 2143.01(VI) states that if the proposed modification or combination changes the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. The replacement of the outer tube of the Wang catheter, and its strategically located exit holes, with a porous membrane would, without question, change the principle of operation of the Wang catheter. For at least this reason, the combination of Wang and Mishra is improper and Applicants respectfully request that the rejection based on this combination be withdrawn.

There Is No Motivation To Combine Martin and Mishra

Claims 18-28 and 73-81 presently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Martin in view of Mishra. Specifically, the Examiner has taken the position that it would have been obvious to combine Martin and Mishra by replacing the outer tube of the Marin dialysis catheter with the outer membrane of the Mishra dialysis probe. Applicants respectfully disagree.

The Martin reference discloses a dialysis catheter including an inner tube and an outer tube interconnected by a pair of axially-extending ribs. The pair of ribs divides a space between the inner and outer tubes into a pair of lumens. One lumen (50) is an extraction lumen, which is configured to allow a fluid to flow from a distal end of the catheter towards a proximal end of the catheter. The other lumen (52) is a return lumen, which is configured to allow a fluid to flow from a proximal end of the catheter towards a distal end of the catheter. Accordingly, a fluid (such as blood) is drawn from the body through the extraction lumen, processed, and then return to the body through the return lumen.

Both lumens communicate with a region external to the catheter through respective ports in the outer tube of the catheter. The ports (44) of the extraction lumen are positioned proximally from the ports (45) of the return lumen. Such a construction reduces the amount of cross-flow

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between the extraction lumen and the return lumen. In other words, it is undesirable for freshly processed blood returned to the body by the return lumen to be immediately drawn into the extraction lumen prior to circulating through the body. Thus, it is advantageous to provide a catheter having discrete, strategically located ports.

With the modification as proposed by the Examiner, fluid flow would be permitted into the extraction lumen and out of the return lumen along a significantly overlapping distance. As a result, significant cross flow would certainly occur. The Martin reference does not contemplate, much less suggest, that the strategically located apertures could be replaced by an outer catheter wall made from a porous membrane, which would allow fluid flow along the entire length of the membrane and permit a significant degree of cross flow.

Furthermore, the catheter of the Martin reference is constructed from an extruded tube, including both the inner and outer tubes, along with the pair of ribs. The tube is cut to length and then the tip (Figure 3) is subsequently formed. *See* column 6, lines 17-41. Applicants cannot determine how the Examiner proposes the outer tube, which is used to form the tip, would be omitted or otherwise removed and replaced by the outer membrane of the Mishra reference. There is no suggestion to separately form the inner tube, ribs and tip of the Mishra catheter.

Because there is no motivation to combine the Martin and Mishra references as proposed by the Examiner, for at least the reasons presented herein, the rejections based on the combination is improper. Accordingly, Applicants respectfully request withdrawal of the rejections based on the combination of Martin and Mishra.

In making the combinations used to reject the present claims, the Examiner has provided no reasonable explanation of a motivation or suggestion, found in the prior art, to do so. The only reasons provided in both instances is that the provision of a membrane, instead of a solid tube with discrete ports, would "enhance porosity properties" of the catheter. In each combination, the proposed modification would drastically alter the performance of the prior art invention being modified and/or would change the principle of operation. Thus, Applicants submit that the motivation for the Examiner making the applied combinations did not come from the prior art, but rather, impermissibly originated from the Applicants own disclosure.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Curtiss C. Dosier at (949) 721-7613 (direct line), to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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